

REMARKS

Claims 1-10 remain pending in the present application. Claims 11-25 are canceled. New claims 26-40 are added, which find basis generally throughout the specification as originally filed. No new matter is added.

In view of the Decision on Appeal, Applicants believe that claims 1, 4 and 6 are allowable as written. In this regard, Applicants request reconsideration of the election of species requirement for all claims ultimately dependent upon claim 1 and previously withdrawn.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 C.F.R. 1.141.

Claim 2 is directed to an active suture comprising a braided suture having an outer diameter and a plurality of interstices along at least a portion of its length, and a tube coaxial with at least a portion of the braided suture having an outer diameter that is less than that of the braided suture and an inner diameter, having one or more openings therein to conduct fluid to the plurality of interstices of the braided suture, wherein the ratio of the outer diameter of the tube to the inner diameter of the tube is greater than 1.7.

The claimed active sutures are often necessarily tied into knots to anchor them into position (specification, page 16, lines 14-15). However, the suture must be designed in such a way to avoid collapse of the internal passageway upon tying of the knots, so as to permit passage of the therapeutic fluid therethrough (page 16, lines 20-26). So it is clear that the sutures of the present invention must be flexible, but designed such that the internal passageway is stiff enough to avoid collapse upon tying into suitable surgical knots.

As such, the ratio of the inner tube OD/ID is preferably greater than 1.7 for most polymeric tubing materials (page 16, line 27, bridging to page 17, line 3).

Rejection under 35 U.S.C. §103(a) over Burton in view of Davis et al.

Claim 2 stands rejected under 35 U.S.C. §103(a) as obvious over Burton (U.S. 4,159,720) in view of Davis et al. (U.S. 3,474,703). Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

The Decision on Appeal

The Board's decision on appeal focuses on the teaching of Davis et al. as to providing an inner hollow braid within an outer braid (FF. 8), the assertion of the Examiner that Davis teaches "an efficient method of transporting...fluid along the length of the wick through capillary action" (FF.9; emphasis added), and that the selection of OD/ID ratio would have been obvious to the skilled artisan.

Applicants respectfully submit that both the Examiner and the Board have overlooked more basic deficiencies in the proposed combination of the teachings of Burton and Davis et al., as discussed below.

Burton indeed discloses (inactive) sutures for delivering a prescribed liquid medicine or other fluid to a subcutaneous tissue. The Burton device incorporates capillary wicks (Abstract), which are designed to transport liquid medicines along their length via capillary action (col. 4, lines 37-42).

As such, Applicants agree that the Burton devices represent analogous art to those of the presently claimed invention. However, as recognized by the

Board, the Burton disclosure has some deficiencies with respect to claim 2 hereof.

In an effort to cure these deficiencies, the Examiner has cited Davis et al., to wit:

Davis et al. (hereinafter Davis) also discloses a braided wick for transmitting fluids (column 1, lines 14-22). The wick advantageously comprises a hollow inner braid within an outer braid where the inner braid comprises openings between the braided filaments (i) (column 3, lines 26-28, 44-45, 68-74). (ii) This provides an efficient method of transporting the fluid along the length of the wick through capillary action (column 3, lines 25-45). Davis teaches the flow of fluids is not restricted in either an axial or radial direction when utilizing a hollow inner tube (column 3, lines 35-36). Therefore, in view of this advantage, it would have been obvious at the time of the invention for the suture/wick of Burton to comprise an inner tube within the inner lumen as disclosed by Davis. (Examiner's Answer, pp. 4-5; Roman numerals and emphasis added).

Applicants respectfully submit that the highlighted portions of the Examiner's quoted language, above, materially misrepresents the nature of the Davis et al. disclosure, and that consideration of Davis et al. "as a whole" would lead the skilled artisan away from the combination of teachings proposed by the Examiner.

The patent law dictates that prior art references must be considered as a whole.

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). **MPEP 2141.03 VI.**

Likewise, it is impermissible to choose from the reference only those teachings which support the proposed rejection.

It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. *In re Wesslau*, 147 USPQ 391, 393 (CCPA 1965).

Applicants submit that a thorough consideration of the Davis et al. reference reveals that the Burton and Davis et al. references are improperly combined as non-analogous prior art, and that the skilled artisan would not have any reason to modify the Burton device in the manner of Davis et al.

Non-analogous art

Davis et al. disclose making a "capillary device" which is rigid and, at the same time, is capable of providing for the flow of liquids in both axial and radial directions, which incorporates coaxial braided structures, which can be used for pen points, wick lubricators and the like (Abstract). However, Davis et al. fails to disclose or suggest a suture assembly whatsoever.

The highlighted portion (i) of the Examiner's quoted rejection, above reveals that the portion of Davis et al. focused-on by the Examiner is directed only to the cross-sectional illustration of Fig. 2 thereof, without consideration of the reference as a whole. At the location cited by the Examiner, Davis et al. disclose:

FIG. 2 illustrates the construction of the device of FIG. 1 in which the braided device 1 is comprised of an outer braid 2 braided around an inner braid 3.

However, immediately above, Davis et al. describe Fig. 1:

FIG. 1 is a side view of the capillary device of this invention;
and
FIG. 2 is a view taken through line 2-2 of FIG. 1.

Referring to FIG. 1, there is shown a braided capillary device 1 suitable for the transmission and application of fluids. One end of the device 1 has been reduced in diameter and given a rounded tip as would be desirable, for example, if the device 1 is to be used as a writing instrument. (Col. 3, lines 17-25; emphasis added).

Davis et al. provide further considerations in making their "capillary device", related to their use only as either "writing instruments" or as "lubricating wicks" (Abstract; col. 2, lines 1-2).

Still another object of this invention is to provide capillary devices having high feed rates that are comprised of a plurality of filaments securely bonded together to provide good mechanical properties of strength, stiffness and wear.

And still another object of this invention is to provide novel means for securing filaments together in the form of improved capillary devices that have high strength and stiffness, good characteristics of wear, good characteristics of fluid transmission, and strong, long wearing applicator points.

And yet another object of this invention is to provide fine, long-wearing tips for writing instruments. (Col. 2, line 64, bridging to col. 3, line 4; emphasis added).

As such, it is clear that the Davis et al. "capillary device" is intended for use as a component of a writing pen, entirely non-analogous as compared both to the presently claimed invention and to that of Burton. In analyzing whether a reference is suitably relied-upon by the Examiner, one consideration is described in *In re Oetiker*.

In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned. *In re*

Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). (Emphasis added).

Clearly, Davis et al. meets neither of the *Oetiker* tests.

By limiting the analysis of Davis et al. to the teachings thereof relating to the cross-sectional representation of Fig. 2, the Examiner and the Board have failed to recognize the non-analogous nature of the reference as compared to the presently claimed invention: i.e. a writing instrument vs. a surgical suture.

Further, the Examiner provides no reason whatsoever to explain why the skilled artisan would look to a reference disclosing a writing instrument (Davis et al.) in order to modify a suture (Burton).

Likewise, on consideration of the Davis et al. reference as a whole, it becomes clear that the problems solved therein are not comparable to the problems solved by the presently claimed invention.

As quoted above, Davis et al. is directed to methods for improving the mechanical properties of fibrous writing instruments, including high strength and stiffness and long term wear. Davis et al. accomplish these goals by

...weaving filaments into a braid and then adhering adjacent filaments of the braid to each other as by the use of heat, solvents, adhesives, or the like. (col. 3, lines 9-12; see also col. 4, lines 57-69).

Thus, the "solution" of the Davis et al. problem is directed to bonding of individual filaments of the braided structure together at their intersection points, and not to providing a central passageway for fluid flow, as suggested by the Examiner.

As such, Applicant s respectfully submit that the Examiner's reading of Davis et al. takes the "teachings" thereof completely out of context of the reference "as a whole". *In re Wesslau, Id.*

Withdrawal of the rejection is requested on this basis alone, since the Davis et al. reference is clearly non-analogous art, both as to the presently-claimed invention and to the base reference to Burton, and as such is improperly combined with Burton.

In view thereof, no *prima facie* case of obviousness can be said to exist.

Flawed Fact Finding

Applicants further submit that both the Examiner's and the Board's findings of fact, in particular FF 9, is unsupported by Davis et al. The Board, quoting the Examiner, states:

FF 9. The Examiner finds that Davis teaches that the configuration of the inner and outer braided filaments "provides an efficient method of transporting...fluid along the length of the wick through capillary action". (Emphasis added).

This finding is simply incorrect. While the Davis et al. devices are characterized throughout the reference as "capillary devices", there is no evidence whatsoever that fluid travels "along the length" thereof by "capillary action". The capillarity of the Davis et al. devices is consistently characterized as that of liquid flowing between the filaments thereof, i.e. in the radial direction of Fig. 2.

As noted above, care must be exercised when bonding the filaments together to avoid excessive blinding of the pores of the braid and the spaces, if any, between the several concentric braids. (Col. 4, lines 64-67; emphasis added).

Another interesting and useful technique by which the degree of open area of the capillaries may be controlled is through the use of interfering materials added to the bonding agent...In some instances, if the interfering materials are porous themselves, it may not be necessary to remove them from the interstices of the braid after the bonding operation has been completed. (Col. 5, lines 23-35; emphasis added).

So while the portion of Davis et al. cited by the Examiner indicates:

...the flow of fluids through the capillary device is not restricted in either an axial or radial direction...(col. 3, lines 35-36),

a more thorough reading of this portion of Davis et al. reveals that the capillary action, *per se*, is conducted through the Davis et al. "capillary device" in the radial direction, i.e. between the contact points of the filaments – the "capillary spaces".

It is thought that when adjacent filaments of the braid are properly bonded together in accordance with the teachings of this invention, the bonding occurs primarily at the intersection of these filaments where essentially point contact is made. It is believed that this prevents the capillary spaces from becoming blinded and thus the flow of fluids through the capillary device is not restricted in either an axial or radial direction. (Col. 3, lines 29-36; emphasis added).

So while fluid flow in the "axial direction" of the "capillary device" is not restricted, there is no indication that such flow is due to capillary action. Likewise, the skilled artisan would know that such a slow delivery of fluid/ink through the length of an ink pen would not be acceptable or desired, and that the internal passageway of the Davis et al. device is merely a reservoir for the ink.

As such, the capillary action of the Davis et al. device is not conducted in the same direction as that of the Burton device, and the skilled artisan, relying on scientific principles and not merely on semantics, would not have drawn any

conclusions as to the equivalence of the fluid flow between the devices of Davis et al. and Burton, nor derived any reason to modify Burton in the manner of Davis et al.

Withdrawal of the rejection is requested on this basis, since the skilled artisan would not have had any reason to combine the Davis et al. reference teachings with those of Burton.

Modification of Burton would destroy the function of the reference

As discussed above, the Burton device is a surgical suture, which by definition must be flexible such that it can be threaded into relatively tight spirals to close a wound and tied into knots.

In contrast, Davis et al. is directed to bonding filaments into a rigid, strong, stiff structure, as quoted above. When considering the Davis et al. teachings "as a whole", the skilled artisan would not look to Davis et al. for motivation to modify the Burton suture materials, since to do so would render the Burton sutures rigid, stiff and non-flexible.

If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984).
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Withdrawal of the rejection is further requested on this basis.

In view of the foregoing, it is respectfully submitted that the present claims are in condition for allowance. Prompt notification of allowance is respectfully requested.

U.S. Serial No. 10/727,367
Response dated: February 10, 2011
Response to Decision dated: December 10, 2010

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 50-2478(14619).

If the Examiner has any questions or wishes to discuss this application, the Examiner is invited to contact the undersigned representative at the number set forth below.

Respectfully submitted,

Date: February 10, 2011

A handwritten signature in black ink, appearing to read "Michael J. Mlotkowski", is written over a horizontal line.

Michael J. Mlotkowski
Attorney for Applicant s
Registration No. 33,020

POST OFFICE ADDRESS to which
Correspondence is to be sent:

Roberts, Mlotkowski, Safran & Cole
P.O. Box 10064
McLean, VA 22102
(703) 584-3270 (voice)
(703) 848-2981 (fax)